

Remarks

Claims 1-3, 7-8, 10, 14-16 and 19-24 are pending. Claims 5, 6, 17 and 18 are cancelled. Claims 1-3, 7-8, 10, 14-16 and 19-24 are rejected.

Claims 1-3, 8, 14-16, 20 and 22-24 are rejected as obvious under 35 USC §103(a) over Amrita. The rejection states that the Amrita essential oil of *Helichrysum italicum* has been commercially available since 1999. The rejection states that the essential oil is distilled from the flower of *Helichrysum italicum*. The rejection states that the amount of neryl acetate in the Amrita *Helichrysum italicum* essential oil is close to “about 40%[.]” The rejection states that the Amrita *Helichrysum italicum* oil is obtained from the same source by the same methods used by the Applicants and that the claims are obvious because there is no patentable distinction between the claimed composition and the prior art.

Claims 1-3, 8, 14-16, 20 and 22-24 are not obvious under 35 USC §103(a) over Amrita. Independent Claims 1 and 14 have been amended to recite the claimed compositions comprise “about 0.1 to about 2.1% by weight of a purified essential oil extracted from flower tops of *Helichrysum italicum* in relation to the weight of the composition” and that “the essential oil comprises 40 to 70% by weight neryl acetate.” Claims 2, 3, 7 and 8 are dependent on independent Claim 1 and incorporates all of its recitations. Claims 14, 16, 20 and 22-24 are dependent on independent Claim 1 and incorporate all of its recitations. Importantly, the Applicants note that amended Claims 1 and 14 no longer recite that the essential oil comprises “about” 40 to 70% by weight of neryl acetate.

First, Amrita fails to teach all the elements of the claimed compositions. The Applicants note that the previously submitted data demonstrates that the compositions of Amrita are different from the claimed compositions and unexpectedly contain different amounts of neryl acetate. Furthermore, Amrita fails to mention the weight amount of *Helichrysum italicum* essential oil in the cosmetic compositions disclosed and one of ordinary skill in the art would not be motivated to make the claimed compositions. The rejection also improperly relies on an inherency argument in an attempt to establish Amrita teaches all the elements of the claimed compositions. This argument is improper because the data previously submitted shows that the claimed compositions are not necessarily the same as those of Amrita. In other words, the rejection acknowledges that Amrita does not expressly teach all the elements of the claimed

compositions and that these compositions and those of Amrita are not necessarily identical. Moreover, it is self evident to state:

“That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.” *See In re Spormann and Heinke*, 150 USPQ 499, 452 (CCPA 1996) (emphasis added).

The Applicants respectfully request withdrawal of the rejections of Claims 1-3, 7, 8, 10, 14-16 and 19-24.

Claims 5, 6, 17 and 18 are rejected as obvious under 35 USC §103(a) over the combination of Amrita and Spina. The rejection states that Amrita does not specify the weight amount of the *Helichrysum italicum* oil in the disclosed compositions. The rejection states that Spina teaches that 1.1-1.3 grams of *Helichrysum italicum* essential oil is used in 30 grams of total preparation which is equivalent to 3.7-4.3 weight percent. The rejection states that Spina discloses a topical composition for scalp and that one of ordinary skill in the art would have been motivated to look to Spina for specific teachings on the amount of the active ingredient suitable for topical application. The rejection then concludes that one of ordinary skill in the art would have discovered a workable range of the active ingredient in the *Helichrysum italicum* essential oil by routine experimentation.

The rejection of Claims 5, 6, 17 and 18 as obvious under 35 USC §103(a) over the combination of Amrita and Spina is now moot in light of the cancellation of these claims. Additionally, amended independent Claims 1 and 14 and the related dependent claims are not obvious, even if the rejection were hypothetically applied to these claims, for the reasons discussed above with regard to Amrita and below with regard to the combination of Amrita and Afriat and because of the other amendments to the claims.

Furthermore, Spina indicates that 1.1-1.3 g of *Helichrysum italicum* essential oil is used in 30 g of its compositions which is equivalent to 3.7-4.3 weight percent of *Helichrysum italicum* essential oil. In the claims, the amount of *Helichrysum italicum* essential oil in the compositions is “about 0.1 to about 2.1% by weight” which is an amount that is significantly lower than what is described in Spina. Additionally, Spina does not teach that the composition has anti-inflammatory, wound healing, and antiseptic effects. Instead, Spina provides a composition comprising vegetable oil (*i.e.* plant oil) and six essential oils, only one of which is *Helichrysum*

italicum essential oil, in an anti-hair loss composition, an anti-itchy scalp composition and a composition promoting the growth of hair. Consequently, Spina's composition is to be used on the scalp and hair of the head, but not on the skin of the face, as an antiwrinkle cosmetic composition.

Importantly, one of ordinary skill in the art would not have been motivated to look to art such as Spina relating to an anti-hair loss composition, an anti-itchy scalp composition or a composition promoting the growth of the hair. In particular, one of ordinary skill in the art would not be motivated to combine or modify the teachings of such art concerning the amount of *Helichrysum italicum* essential oil or other active ingredients, such as neryl acetate, for using in an anti-wrinkle cosmetic composition. This is because inducing thick, luxuriant hair growth on the face and preventing hair loss on the face are not desirable properties in an anti-wrinkle cosmetic composition to be applied topically to the face and other visible portions of the body.

The skilled artisan would also not have been motivated by Amrita or Spina to decrease the concentration of *Helichrysum italicum* essential oil included these compositions. Instead, the skilled artisan would expect that the efficiency of such compositions would decrease when the amount of *Helichrysum italicum* essential oil included in the composition is decreased. Furthermore, one of ordinary skill in the art would not expect that the compositions of the claims having such small amounts of *Helichrysum italicum* essential oils, relative to Spina, would be capable of generating a drastic increase in type-I collagen production. Indeed, the compositions of the claims comprising 0.7% by weight of *Helichrysum italicum* essential oil, when provided at a concentration in the culture medium of 0.05 % v/v allows fibroblasts to synthesize up to six times more type-I collagen. *See e.g.* paragraphs [0067], [0043], [0079] and Figure 1 of the filed application referring to "compositions for the face"). Last, the Applicants note that such fibroblast collagen production experiments are accepted in the art as showing and predicting the anti-wrinkle and anti-aging activity of compositions. The Applicants respectfully submit that amended independent Claims 1 and 14 and the related dependent claims are not hypothetically obvious under 35 USC §103(a) over the combination of Amrita and Spina for the reasons discussed above.

Claims 7, 10, 19 and 21 are rejected as obvious under 35 USC §103(a) over the combination of Amrita and Afirat. The rejection states that Amrita does not teach nanosphere formulations or the additives "natural perhydro-squalene, sucroesters, borage oil, oenothera oil,

grapestone oil, vitamin A, vitamin E and allantoin.” The rejection states that Afirat teaches nanosphere formulations comprising ascorbic acid, vitamin E and other essential oils. The rejection states that one of ordinary skill in the art would have been motivated by Afirat to modify the teachings of Amrita by incorporating *Helichrysum italicum* essential oil and vitamin E into nanospheres. The rejection states that this is because the inventions of Amrita and Afirat are in the cosmetics art. The rejection then concludes that one of ordinary skill in the art would have had a reasonable expectation of successfully producing a stable composition comprising *Helichrysum italicum* essential oils in the nanospheres.

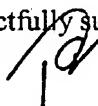
Claims 7, 10, 19 and 21 are not obvious under 35 USC §103(a) over the combination of Amrita and Afirat. First, Afirat fails to correct the deficiencies of Amrita discussed in detail above. This means that the combination of Amrita and Afirat fails to render the compositions of Claims 7 or 10 obvious under 35 USC §103(a). Additionally, this means that the combination of Amrita and Afirat fails to teach the claimed methods of cosmetic skin care using these compositions. This is because this combination of references fails to teach all the elements of the claimed compositions and methods and, consequently, one of ordinary skill in the art would not be motivated to combine these references or have a reasonable expectation of success on doing so. The Applicants respectfully request withdrawal of the rejections of Claims 7, 10, 19 and 21 under 35 USC §103(a).

In summary, the composition and method claims of the application are not obvious under 35 USC §103(a) over Amrita or the combination of Amrita and Afirat or Spina, because:

- 1) the claims recite a *Helichrysum italicum* essential oil having a high percentage of neryl acetate relative to the cited art;
- 2) the amount of *Helichrysum italicum* essential oil in the compositions is lower than what one of ordinary skill in the art would have expected; and
- 3) the cosmetic compositions have unexpected properties in treating skin aging effects (e.g. strongly stimulating type I collagen production) despite containing smaller amounts of *Helichrysum italicum* essential oil than the cited art. *See e.g.* paragraph [0017] of the filed application.

In light of the foregoing, the Applicants respectfully submit that the entire application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,


T. Daniel Christenbury
Reg. No. 31,750
Attorney for Applicants

TDC/vbm
(215) 656-3381